In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: February 3, 2014

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JOHN G. RUPERT,	*	
	*	No. 10-160V
Petitioner,	*	Special Master Dorsey
	*	
v.	*	Entitlement; Guillain-Barré
	*	syndrome ("GBS"); Tetanus-
SECRETARY OF HEALTH	*	diphtheria-acellular-pertussis
AND HUMAN SERVICES,	*	("Tdap") vaccine; Alternative causation;
	*	Upper respiratory tract infection
Respondent.	*	
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Franklin John Caldwell, Jr., Maglio, Christopher & Toale, Sarasota, FL, for petitioner; Althea Walker Davis, U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

I. Introduction

On August 9, 2011, John G. Rupert ("petitioner") filed a petition for compensation under the National Vaccine Injury Compensation program ("the Program")[2] in which he alleged that a tetanus-diphtheria-acellular-pertussis ("Tdap") vaccine he received on May 21, 2008, caused him to develop Guillain-Barré syndrome ("GBS"). See Joint Submission of Uncontested Facts and Issues to Be Addressed at Hearing ("Stip. of Facts"), filed Aug. 30, 2013, at 1. Respondent

[1] Because this published decision contains a reasoned explanation for the action in this case, the undersigned intends to post this decision on the website of the United States Court of Federal Claims, in accordance with the E-Government Act of 2002 § 205, 44 U.S.C. § 3501 (2012). In accordance with the Vaccine Rules, each party has 14 days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b); see also 42 U.S.C. § 300aa-12(d)(4)(B). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted decision. If, upon review, the undersigned agrees that the identified material fits within the requirements of that provision, such material will be redacted from public access.

[2] The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 et seq. (2012) ("the Act"). Hereafter, individual section references will be to 42 U.S.C. § 300aa.

recommended against compensation, stating that petitioner has not presented adequate evidence to show that petitioner's vaccination caused his GBS. See Respondent's Report ("Resp't's Rep't"), filed Oct. 18, 2010, at 11-12. Further, respondent alleged that "the evidence . . . indicates that petitioner's condition was caused by a viral illness and not caused by vaccination." Id. at 12. The parties submitted expert reports and an entitlement hearing was held in Washington, DC, on October 3, 2013, during which the parties' experts testified. The parties requested to file post-hearing briefs, which were filed on December 6, 2013.

After a review of the entire record, § 300aa-13(a)(1), the undersigned finds that petitioner has failed to provide preponderant evidence that his May 21, 2008 Tdap vaccine caused his GBS. Because petitioner did not meet his burden of proof on causation, respondent does not have the burden of establishing a factor unrelated to the vaccination caused petitioner's injuries. See Doe v. Sec'y of Health & Human Servs., 601 F.3d 1349, 1358 (Fed. Cir. 2010) ("[petitioner] Doe never established a prima facie case, so the burden (and attendant restrictions on what 'factors unrelated' the government could argue) never shifted"). Bradley v. Sec'y of Health & Human Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993). Nevertheless, respondent has identified an alternative cause of petitioner's injuries – petitioner's upper respiratory tract infection.

Therefore, even if petitioner had established his case by a preponderance of the evidence, his arguments fail because respondent has proven that petitioner's upper respiratory tract infection is the sole cause of his GBS. Accordingly, petitioner is not entitled to compensation and his petition must be dismissed.

II. Factual Background

A. Issues to be Decided

Prior to the hearing, the parties filed a joint submission "identifying (1) stipulated facts; (2) facts in dispute; (3) issues not in dispute; and (4) issues remaining to be resolved." Joint Stip. at 1. These are addressed in turn below.

The parties stipulate that petitioner received his Tdap vaccine on May 21, 2008. Id. The parties also stipulate that on June 25, 2008, petitioner sought treatment for a "three week history of upper respiratory symptoms." Id. (quoting Petitioner's Exhibit ("Pet'r's Ex.") 2 at 3[3]). The parties stipulate that petitioner developed GBS approximately five weeks after he received his Tdap vaccine. Id. (citing Pet'r's Ex. 4 at 62). Lastly, the parties stipulate that there are no facts in dispute. Id.

The parties do not dispute that the sequelae of petitioner's GBS lasted for more than six months. Id. The parties also do not dispute that petitioner's claim was timely filed and that he received a vaccine covered by the Act. Id. at 1-2.

The parties stipulate that the only issue in dispute is "whether the Tdap vaccine administered to Petitioner on May 21, 2008, was the legal cause of his GBS." Id. Thus, this

[3] All references to petitioner's exhibits are to the Bates stamp pagination.

decision addresses the issue of whether petitioner has provided preponderant evidence demonstrating that his May 21, 2008 Tdap vaccination caused his injuries.

B. Petitioner's Medical History

Petitioner was born on May 15, 1965. Pet'r's Ex. 2 at 4. Petitioner's medical history prior to his May 21, 2008 vaccination is generally unremarkable. Notably, however, petitioner received a prior tetanus vaccine without any apparent adverse reaction. See id. at 7 (note from May 2, 2002, that petitioner's "[l]ast tetanus was 3 years ago").

On May 21, 2008, petitioner received the Tdap vaccine at issue. Id. at 3. There is no indication in the record that petitioner had any immediate adverse reaction to the vaccine. On June 25, 2008, petitioner presented to his primary care provider, Todd Fox, M.D., due to "a three-week history of persistent upper respiratory symptoms." Id. Dr. Fox noted that petitioner reported sinus congestion, headache, fever, and cough. Id. Dr. Fox also observed that petitioner's oropharynx was "mildly erythematous"[4] and his neck had "shotty anterior adenopathy."[5] Id. Dr. Fox diagnosed petitioner with "[p]ersistent [upper respiratory infection]/sinusitis" and prescribed Augmentin, an antibiotic. Id. What caused petitioner's upper respiratory tract infection is unknown.[6]

On June 27, 2008, petitioner presented to Liberty Hospital in Liberty, Missouri, with complaints of a four- to five-day history of bilateral foot tingling. Pet'r's Ex. 4 at 41. Petitioner reported difficulty using his legs for approximately 24-48 hours. Id. He was diagnosed with "gait disturbance." Id. at 42. James Olson, M.D., diagnosed petitioner with "[a]taxia[7] of uncertain etiology, possibly infectious." Id. at 47. Dr. Olson noted that petitioner had "[r]ecent sinusitis" and had been "given Augmentin two days ago." Id.

Salman Malik, M.D., a neurologist, evaluated petitioner on June 27, 2008. Dr. Malik noted petitioner's two- to three-week history of an upper respiratory tract infection with sinus congestion, cough, drainage, nasal stuffiness, and general malaise. Id. at 66, 69. Based on petitioner's history and condition, Dr. Malik indicated that "the main diagnostic concern is for acute post infectious inflammatory demyelinating polyneuropathy such a[s] Guillain-Barré syndrome." Id. at 69. Dr. Malik stated that

[4] Erythema is "redness of the skin produced by congestion of the capillaries." Dorland's Illustrated Medical Dictionary (32d ed. 2012) ("Dorland's") at 643.

[5] Adenopathy (also called lymphadenopathy) is swelling of the lymph nodes. See Dorland's at 1083.

[6] The parties agree that what caused petitioner's upper respiratory tract infection is unknown. See tr. 17, 171.

[7] Ataxia is "failure of muscular coordination; irregularity of muscular action." Dorland's at 170.

> [i]t should be noted that other infectious etiologies need to be considered as a potential cause for infectious polyneuritis. These include herpes simplex, varicella zoster (the patient has had previous shingles but not recently) and among others West Nile Virus disease. He has had several insect bites and tic bites. Lyme disease is unlikely in this scenario, although initial presentation can be with Guillain-Barré syndrome in that condition.

Id. Cerebrospinal fluid tests were negative for herpes simplex virus, Lyme disease, varicella zoster virus, West Nile virus, syphilis, cytomegalovirus, cryptococcal antigen, Rocky Mountain Spotted Fever, and bacterial culture. Id. at 479-91. Dr. Malik diagnosed petitioner's condition as "probably post infectious AIDP."[8] Id. at 589. Dr. Malik did not identify petitioner's Tdap vaccination as a possible cause for his GBS.

On June 28, 2008, Raghavendra Adiga, M.D., infectious disease specialist, noted that petitioner presented "with an acute onset of bilaterally symmetrical extremity weakness and ataxia with a recent upper respiratory infection preceding." Id. at 64. Dr. Adiga considered the "most likely diagnosis . . . [to] be Guillain-Barré syndrome or acute post infectious inflammatory demyelinating polyneuropathy," but found no "evidence of other active ongoing infections at . . . th[e] time." Id.

Dr. Adiga observed petitioner again on July 2, 2008. Id. at 588. His diagnosis on that day was GBS. Dr. Adiga stated that "[w]hile [the tetanus] vaccine could have triggered [petitioner's GBS] (little too long), odds are viral URI more likely." Id. Nonetheless, Dr. Adiga ordered that a VAERS[9] report be completed for petitioner, which was submitted on July 2, 2008. Id.; Pet'r's Ex. 8 at 1.

Dr. Malik saw petitioner again on July 2, 2008. He reiterated his impression that petitioner's condition was "probably postinfectious." Pet'r's Ex. 4 at 589.

On July 7, 2008, Dale Wytock, M.D., stated petitioner was "currently in the ICU with Guillain-Barré syndrome." Id. at 52. Dr. Wytock concluded that petitioner's "[e]levated liver enzymes [were] probably related to medication," but indicated that they "could be related to a virus." Id. at 53.

On July 17, 2008, petitioner had a gastrointestinal consultation. Id. at 567. The gastroenterologist questioned whether some of petitioner's increased liver function tests were related to his medications or a virus. Id.

Dr. Fox saw petitioner for a follow-up examination on June 10, 2010. Pet'r's Ex. 7 at 1. Dr. Fox recorded petitioner's past medical history as "[GBS] following tetanus immunization." Id.

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[8] Acute inflammatory demyelinating polyneuropathy ("AIDP") is another term for GBS. See tr. 118.

[9] "VAERS" refers to the Vaccine Adverse Event Reporting System.

C. Guillain-Barré Syndrome

GBS is a "rapidly progressive ascending motor neuron paralysis of unknown etiology, frequently seen after an enteric or respiratory infection. Dorland's at 1832. Individuals afflicted with GBS present

> with paresthesias of the feet, followed by flaccid paralysis of the entire lower limbs, ascending to the trunk, upper limbs, and face; other characteristics include slight fever . . . absent or lessened tendon reflexes, and increased protein in the cerebrospinal fluid without a corresponding increase in cells.

Id.

The cause of GBS has not been definitively established. See Pet'r's Ex. 11[10] at 4. But "[a]n autoimmune mechanism following viral infection has been postulated," Dorland's at 1832, and "[n]umerous case reports and descriptions of large series have implicated a plethora of different infections and other events as possible antecedents of GBS." Pet'r's Ex. 11 at 4. "Studies in patients and animals have provided convincing evidence that GBS, at least in some cases, is caused by an infection-induced aberrant immune response." Respondent's Exhibit ("Resp't's Ex.") C[11] at 3.

GBS is "commonly associated with some antecedent event, such as an upper respiratory tract infection." Pet'r's Ex. 12[12] at 1; see also Resp't's Ex. C at 1 ("GBS is most commonly a post-infectious disorder"). "About two-thirds of patients have symptoms of an infection in the 3 weeks before the onset of weakness . . . . In most GBS studies, symptoms of a preceding infection in the upper respiratory tract or gastrointestinal tract predominate." Resp't's Ex. C at 2.

III. Discussion

The Vaccine Act established the Program to compensate vaccine-related injuries and deaths. § 300aa-10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Human Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

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[10] R.A.C. Hughes et al., "Pathogenesis of Guillain-Barré syndrome," 100 J. Neuroimmunology 74 (1999). Respondent filed this article as Respondent's Exhibit D.

[11] Pieter A. van Doorn et al., "Clinical features, pathogenesis, and treatment of Guillain-Barré syndrome," 7 Lancet Neurology 939 (2008).

[12] J.D. Pollard & G. Selby, "Relapsing Neuropathy Due to Tetanus Toxoid," 37 J. Neurological Sciences 133 (1978).

A. Standards for Adjudication

Petitioner's burden of proof is a preponderance of the evidence. § 300aa-13(a)(1). The preponderance of the evidence standard, in turn, has been interpreted to mean that a fact is more likely than not. Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 n. 2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). A petitioner who satisfies this burden is entitled to compensation unless the government can prove, by a preponderance of the evidence, that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine." § 300aa-13(a)(1)(B).

B. Elements of petitioner's claim

To receive compensation under the Program, petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that he received, or (2) that he suffered an injury that was actually caused by the Tdap vaccine. See §§ 300aa-13(a)(1)(A) and 11(c)(1); Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Petitioner must show that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)).

Because petitioner does not allege he suffered a Table injury, he must prove that the Tdap vaccine he received caused his injury. To do so, he must establish, by preponderant evidence: (1) a medical theory causally connecting the vaccine and his injury ("Althen Prong One"); (2) a logical sequence of cause and effect showing that the vaccine was the reason for his injury ("Althen Prong Two"); and (3) a showing of a proximate temporal relationship between the vaccine and his injury ("Althen Prong Three"). Althen v. Sec'y of Health & Human Servs., 418 F.3d 1275, 1278 (Fed. Cir. 2005); § 300aa–13(a)(1).

The causation theory must relate to the injury alleged. Thus, a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the vaccinee's case, although the explanation need only be "legally probable, not medically or scientifically certain." Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994). Petitioner cannot establish entitlement to compensation based solely on his assertions. Rather, a vaccine claim award must be supported either by medical records or by the opinion of a competent physician. § 300aa-13(a)(1). In determining whether petitioner is entitled to compensation, the special master shall consider all material contained in the record, § 300aa-13(b)(1), including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation . . . of the petitioner's illness." § 300aa-13(b)(1)(A). The undersigned must weigh the submitted evidence and the testimony of the parties' offered experts and rule in petitioner's favor when the evidence weighs in his favor. See Moberly, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence"); Althen, 418 F.3d at 1280-81 ("close calls" are resolved in petitioner's favor).

i. Althen Prong One: Petitioner's Medical Theory

Under Althen Prong One, petitioner must set forth a medical theory explaining how the received vaccine could have caused his alleged injury. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1375 (Fed. Cir. 2009). Under this prong, petitioner must make a showing that the received vaccine can cause the alleged injury. Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1355-56 (Fed. Cir. 2006).

Petitioner's theory of causation must be informed by a "sound and reliable medical or scientific explanation." Id. at 548; see also Veryzer v. Sec'y of Health & Human Servs., 98 Fed. Cl. 214, 223 (2011) (noting that special masters are bound by both § 300aa-13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both "relevant" and "reliable"). If petitioner relies upon a medical opinion to support his theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen v. Sec'y of Health & Human Servs., 618 F. 3d 1339, 1347 (Fed. Cir. 2010) ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."); Perreira v. Sec'y of Health & Human Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) ("An expert opinion is no better than the soundness of the reasons supporting it.") (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980)).

a. Petitioner's Expert, Dr. David Younger

David Younger, M.D., a neurologist, submitted two expert reports and testified on behalf of petitioner. Pet'r's Exs. 9 and 13. Dr. Younger received his bachelor's degree from the University of Michigan in 1976 and his medical degree from Columbia University in 1981. Pet'r's Ex. 9 at 1. He completed residencies in internal medicine and neurology in 1981 and 1984, respectively. Id. He is board-certified in internal medicine, clinical neurophysiology, neurology, and electrodiagnostic medicine. Pet'r's Ex. 9 at 1; tr. 6.

Dr. Younger is a professor of neurology at New York University and also maintains a clinical practice, and sees "[p]rincipally neuromuscular patients." Tr. 7. He has seen patients with GBS. Tr. 7. His publications are "mainly in the realm of neuromuscular disease, nerve and muscle disorders, [and] neuroimmunology." Tr. 8. He has also served as an editor of the textbook Motor Disorders since 1999. Tr. 8.

Dr. Younger opined that petitioner's May 21, 2008 Tdap vaccination caused his GBS. See Pet'r's Ex. 9 at 3; Pet'r's Ex. 13 at 1. Dr. Younger testified that he was unsure whether the Tdap vaccine petitioner received contained a live virus:

> [Ms. Davis]: . . . Is the TDaP vaccine that Mr. Rupert received a live viral vaccine?
> [Dr. Younger]: I don't think so, but I'm not sure.
> Q: It's tetanus toxoid—contains tetanus toxoid, diphtheria toxoid, and acellular pertussis. And would you agree that toxoid means it's inactivated?
> A: Correct.
> Q: So, it is not a live virus vaccine. Is it a viral vaccine at all?

A: Can you clarify what you mean by a "viral vaccine at all"?
Q: Well, is . . . the TDaP vaccine a viral vaccine?
A: You mean does it derive from viral—I'm not sure if I understand.
Q: Right. Is it derived from viral—does it have viral components?
A: I'm not sure.

Tr. 47-48.

Dr. Younger offered three mechanisms of causation: (1) experimental autoimmune neuritis ("EAN"); (2) molecular mimicry; and (3) dual infection genesis. Pet'r's Ex. 9 at 3. Although Dr. Younger indicated that "the mechanism for tetanus-caused GBS" is unknown, tr. 36, he considers all three of his proposed mechanisms to be equally plausible. Tr. 36. His theories are discussed below.

1. Experimental Autoimmune Neuritis ("EAN")

Dr. Younger stated that "[t]he etiopathogenesis of GBS resembles that of [EAN]." Pet'r's Ex. 9 at 3. Dr. Younger explained EAN as "an animal model of the origination of . . . an inflammatory neuropathy[13] . . . derived from experimentally manipulating animals and injecting [them with] certain antigenic[14] substances." Tr. 37. Dr. Younger testified that EAN is "a good model for GBS" because "it's an injectable scenario, and it stimulates the immune system." Tr. 37.

Researchers generally experiment on mice and rabbits. Tr. 38. The researchers "give [animals] myelin[15] basic proteins, or something like that, and myelin is the antigenic substance. So, demyelination occurs." Tr. 37-38. Citing the Hughes article (Pet'r's Ex. 11) in support, Dr. Younger explained that EAN occurs when a "complement dependent cell mediated autoimmune insult targets Schwann cell surface antigens." Pet'r's Ex. 9 at 3. Dr. Younger, however, did not explain how the Hughes article supported his opinion.

Dr. Younger further explained that researchers will then

follow the animals over a short time course, analogous to what might happen in a human subject, and they look at the neurophysiology, if they can; they look at . . . the pathology

[13] Neuropathy is "a functional disturbance or pathological change in the peripheral nervous system." Dorland's at 1268.

[14] An antigen is "any substance capable, under appropriate conditions, of inducing a specific immune response and of reacting with the products of that response." Id. at 103.

[15] Myelin is "the substance of the cell membrane of Schwann cells that coils to form the myelin sheath." Id. at 1218. The myelin sheath is "the cylindrical covering of the axons of some neurons." Id. at 1701.

> of the nerves; and they find that it's reminiscent of an inflammatory autoimmune mechanism.

Tr. 37. The animals generally develop peripheral demyelination. Tr. 38, 40.

When asked whether a vaccine could induce EAN, Dr. Younger acknowledged that he did not "have th[e] expertise to say whether it would work or not." Tr. 38. He acknowledged that animal studies such as EAN could only be applied to humans "[t]o a degree" because "[a]nimals are . . . different." Tr. 39. As a mechanism to explain how the Tdap vaccine causes GBS, Dr. Younger considers his theory of EAN to be "within the realm of possibility." Tr. 40.

Dr. Younger is not aware of experiments whereby vaccines have been used to induce EAN. Tr. 38-39. Likewise, he did not know of any studies that support EAN as an explanation for how a Tdap vaccine could cause GBS. Tr. 38-39.

2. Molecular Mimicry

Dr. Younger's second proposed theory of causation is molecular mimicry. Molecular mimicry is

> sequence and/or conformational homology[16] between an exogenous agent (foreign agent) and self-antigen leading to the development of tissue damage and clinical disease from antibodies[17] and T cells[18] directed initially against the exogenous agent that also react against self-antigen.

Resp't's Ex. I, Institute of Medicine, Adverse Effects of Vaccines: Evidence and Causality 70 (Kathleen Stratton et al. eds., 2012) ("IOM Report").

Dr. Younger explained that his proposed theory of molecular mimicry "works by activating the immune system against determinants that are on the peripheral nerve or thereabouts . . . which foster[s] . . . an autoimmune attack." Tr. 20. According to Dr. Younger, the antigens contained in petitioner's vaccine cross-reacted with his myelin sheath, causing demyelination that led to his GBS. See tr. 50-51.[19]

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[16] Homology is "the quality of being homologous; the morphological identity of corresponding parts." Dorland's at 868.

[17] An antibody is "an immunoglobulin molecule that has a specific amino acid sequence by virtue of which it interacts only with the antigen that induced its synthesis in cells." Id. at 100.

[18] T cells are the cells that are "primarily responsible for cell-mediated immunity." Id. at 324, 1084.

[19] Respondent's expert, Dr. Vinay Chaudhry, considered Dr. Younger's explanation of molecular mimicry at the hearing to be "pretty accurate." Tr. 131. Dr. Chaudhry's "simplest way of explaining [molecular mimicry," is as follows:

Although Dr. Younger opined that molecular mimicry had been "substantiated" as a theory explaining how infections can cause autoimmune disorders, he was unaware if molecular mimicry had been "substantiated" with respect to vaccines causing GBS. Tr. 62. Dr. Younger also acknowledged that there is no published evidence showing that molecular mimicry occurs between the Tdap vaccine and the myelin sheath. Tr. 55, 62. Additionally, Dr. Younger did not explain how molecular mimicry would operate to cause GBS where a vaccination is followed by an upper respiratory tract infection, as occurred in this case.

In his expert reports, Dr. Younger cited two articles to support his theory of molecular mimicry. Pet'r's Ex. 9 at 3 (citing the Pollard article, Pet'r's Ex. 12); Pet'r's Ex. 13 at 3.[20] During the hearing, however, Dr. Younger stated that one of the articles (the Pollard article, Pet'r's Ex. 12) did not support his theory. Tr. 72. He conceded that, based on the Pollard article, petitioner should have had a reaction to the tetanus vaccine each time he received it, but there is no evidence to suggest that petitioner had an adverse reaction to his prior tetanus vaccination. Tr. 90. Moreover, the subject in the Pollard study did not have GBS; he had a chronic inflammatory demyelinating neuropathy. See Resp't's Ex. G at 3; tr. 149. Dr. Younger also acknowledged that the second article (the Kohm article, Pet'r's Ex. 14) does not discuss either GBS or vaccines and does not suggest that GBS could be caused via molecular mimicry. Tr. 55.

3. Dual Infection

Dr. Younger's third theory of causation is "dual infection genesis." Pet'r's Ex. 9 at 3. Dr. Younger posits that a vaccinee will have an enhanced immune response to a vaccine if he or she later develops an infection. Tr. 42-44; Pet'r's Ex. 9 at 3. According to Dr. Younger, the

> temporality would be vaccine, infection, [GBS]. It couldn't go the other way. I wouldn't imagine that one could have a nonspecific URI or sinusitis and then have vaccine and then lead to [GBS] . . . I think the vaccine has to come first.

Tr. 44. Dr. Younger opined that petitioner's Tdap vaccine caused his GBS because, in part, his upper respiratory tract infection "act[ed] as a modifier, perhaps augmenting the immune response or in some way modifying it towards an outcome which ends as [GBS]." Tr. 15-16.

> a molecule with an antigen within this infection mimics the molecule in the nerve. So, if you generate an immune response against the bug, the infection, that immune response not only kills the bug, but because it mimics the nerve, it attacks the nerve, too, and damages the nerve.

Tr. 131.

[20] Citing Pet'r's Ex. 14, Adam P. Kohm et al., "Mimicking the way to autoimmunity: an evolving theory of sequence and structural homology," 11:3 TRENDS in Microbiology 101 (2003).

When asked what type(s) of infection(s) are applicable to his theory, Dr. Younger stated that he has "only applied [the dual infection theory] . . . to this one case." Tr. 42. Dr. Younger conceded that "[t]here is really no evidence at all [to support the theory] other than the opinion that [he] . . . crafted for this case," tr. 49, and the soundness of the theory was just his personal "belief." Tr. 46.

Dr. Younger testified in pertinent part:

> [Ms. Davis] Doctor, even assuming that dual infection genesis is a plausible explanation for tetanus causing GBS in this case, you would agree that there's very little evidence that it applies here.
> [Dr. Younger]. I would say that there's little published evidence, but I think the -- the circumstantial factors here weigh very heavy in that likelihood.
> Q. And you say there's no published evidence. There is really no evidence at all other than the opinion that you crafted for this case.
> A. For the dual pathogenesis?
> Q. For dual infection genesis.
> A. That's true.

Tr. 49.

b. Respondent's Expert, Dr. Chaudhry

Vinay Chaudhry, M.D., a neurologist, testified on behalf of respondent. Dr. Chaudhry completed his undergraduate education at Delhi University in 1975 and completed his graduate education at All India Institute of Medical Sciences in 1980. Resp't's Ex. B at 1. Between 1984 and 1987, Dr. Chaudhry completed residencies in neurology. Id. at 2. From 1987 to 1989, he was a fellow in neuromuscular diseases. Id. at 2. He is board-certified in neurology, clinical neurophysiology, neuromuscular medicine, and electrodiagnostic medicine. Tr. 109; Resp't's Ex. B at 27. Dr. Chaudhry has taught neurology at Johns Hopkins University School of Medicine since 1989. Resp't's Ex. B at 3. He has published extensively in the field of neurology. Tr. 110; Resp't's Ex. B at 3-15. Dr. Chaudhry also maintains a clinical practice, where he sees patients with neurological problems, such as GBS. Tr. 111-12.

Dr. Chaudhry opined that petitioner's GBS was caused by an upper respiratory tract infection, [21] not his Tdap vaccine. See Resp't's Ex. A at 3. Further, Dr. Chaudhry opined that "there is little evidence to support causal association of any vaccine to GBS." Id. at 4. According to Dr. Chaudhry, there is no "evidence-based medicine" demonstrating that the Tdap vaccine can cause GBS. Tr. 124. Dr. Chaudhry has never seen a patient develop GBS after a Tdap vaccine and he has never seen any literature that suggests a causal relationship. Tr. 125, 143-44.

[21] Dr. Chaudhry's opinion that petitioner's upper respiratory tract infection caused his GBS is discussed more fully in section III.C below.

Dr. Chaudhry rejected all three of Dr. Younger's theories. Dr. Chaudhry testified that "EAN is a good model for GBS . . . but it does not have any relevance to [the] Tdap vaccine." Tr. 130. Likewise, Dr. Chaudhry opined that there was no evidence to support Dr. Younger's theory of molecular mimicry. Tr. 131.[22]

Dr. Chaudhry was unfamiliar with Dr. Younger's dual infection genesis theory. Tr. 132. He had not encountered the theory until reading Dr. Younger's reports in this case. Tr. 133. Dr. Chaudhry rejected the theory because it is premised on the assumption that the Tdap vaccine can cause GBS. Tr. 133. Moreover, if the theory were sound, then it would appear in medical literature because "people get infections and vaccines all the time." Tr. 133. Dr. Chaudhry has not seen the issue discussed in any medical literature. Tr. 132.

c. Evaluation of the Evidence

The undersigned finds that petitioner has failed to establish by a preponderance of the evidence that the Tdap vaccine can cause GBS under the facts of this case. Dr. Younger appeared to lack basic knowledge of the Tdap vaccine. Specifically, Dr. Younger did not know whether the Tdap vaccine contains a live virus. See tr. 47, 48-49. This calls into question the reliability of Dr. Younger's opinion.

Petitioner provided no evidence that Dr. Younger's EAN theory is a valid explanation for how the Tdap vaccine can cause GBS. In support of this theory, Dr. Younger cited the Hughes article without meaningful explanation. The authors of the Hughes article discussed a number of infections which are thought to cause GBS, but tetanus was not suggested by the authors as a potential cause. Further, the authors do not discuss EAN. And the authors indicated that epidemiological evidence had "exonerated . . . tetanus toxoid . . . from being [a] statistically significant precipitant[] of GBS." Pet'r's Ex. 11 at 4; see Andreu, 569 F.3d at 1380 (holding that, although petitioners "need not produce . . . epidemiological evidence to establish causation . . . special master[s] can consider it").

Under the facts of this case, where there was no immediate adverse reaction after the Tdap vaccine and petitioner had a subsequent upper respiratory tract infection temporally associated with GBS, Dr. Younger could not persuasively explain how the tetanus vaccine could cause GBS via molecular mimicry. Tellingly, Dr. Younger stated he did not have any evidence that shows the Tdap vaccine can cause GBS via molecular mimicry. Tr. 52. Dr. Younger stated that it is known "that it does happen on occasion," tr. 52, but he could not point to any evidence to support this proposition. Likewise, Dr. Younger agreed that homology "plays a key role in the theory of molecular mimicry," tr. 51, but could not point to any evidence of homology between any component in the Tdap vaccine and a component of the human body, specifically, the myelin sheath. Tr. 55; see also tr. 59-61.

[22] According to Dr. Chaudhry, infectious agents have been shown to cause GBS via molecular mimicry, but there is no evidence that the Tdap vaccine can do so. Tr. 131-32; see also Resp't's Ex. F at 4-8 (discussing that some vaccines, but not tetanus, could cause GBS via molecular mimicry). In fact, as discussed below, Dr. Chaudhry believes that molecular mimicry is the mechanism by which an upper respiratory tract infection can cause GBS.

The Pollard article (Pet'r's Ex. 12) cited by Dr. Younger does not support his theory that a Tdap vaccine can cause GBS via molecular mimicry. The Pollard article documents "[a] unique case history . . . [of a] patient who suffered three episodes of demyelinating neuropathy, each of which followed an injection of tetanus toxoid." Pet'r's Ex. 12 at 1. The IOM subsequently reviewed the study and determined that the individual had chronic inflammatory demyelinating polyneuropathy. See Resp't's Ex. G at 3; tr. 149. Notably, the authors of the Pollard article "did not rule out other possible causes [of the subject's illness] (e.g. viral illnesses) and did not provide evidence beyond a temporal relationship between administration of the [tetanus] vaccine and the development of symptoms after vaccination." Resp't's Ex. G at 3; see also Isaac v. Sec'y of Health & Human Servs., No. 08-601V, 2012 WL 3609993, at *20-21 (Fed. Cl. Spec. Mstr. July 30, 2012) (discussing petitioner's expert's "misplaced reliance" on the Pollard article to support theory that tetanus can cause GBS via molecular mimicry), aff'd, ___ Fed. App'x ___, 2013 WL 5952008 (Fed. Cir. 2013).

Dr. Younger essentially conceded that his dual infection genesis theory has no support. Tr. 41. He created the theory for the purpose of testifying in this case and acknowledged that the theory is not based in scientific literature or studies, has not appeared in any published medical literature, and that he has applied the theory only to this case. Dr. Younger has not taught the theory or used it in his clinical practice. Tr. 41-42.

Simply stated, petitioner has not provided preponderant evidence to corroborate Dr. Younger's proposed theories of causation relevant to the circumstances of this specific case. And his testimony alone does not provide preponderant evidence. See Moberly v. Sec'y of Health & Human Servs., 85 Fed. Cl. 571, 596 (2009) (citing Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997) (special masters are not required to accept the ipse dixit of an expert), aff'd, 592 F.3d 1315 (Fed. Cir. 2010). Accordingly, petitioner has failed to satisfy Althen Prong One.

i. Althen Prong Two: Logical Sequence of Cause and Effect

Under Althen Prong Two, a petitioner must prove that there is a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Capizzano, 440 F.3d at 1324 (citing Althen, 418 F.3d at 1278). "Petitioner must show that the vaccine was the 'but for' cause of the harm . . . or in other words, that the vaccine was the 'reason for the injury.'" Pafford, 451 F.3d at 1356 (citations omitted).

a. Petitioner's Expert, Dr. Younger

In Dr. Younger's view, the only "two possible singular etiological causes of [petitioner's] GBS . . . [were his] vaccination and sinusitis." Pet'r's Ex. 13 at 3. Although Dr. Younger did not dispute that an upper respiratory tract infection can cause GBS and that petitioner had a three-week history of upper respiratory tract infection and sinusitis, tr. 70, Dr. Younger rejected respondent's argument that petitioner's upper respiratory tract infection was the cause of his GBS. See Tr. 17-18, 19, 21, 26, 76. Dr. Younger conceded that petitioner's upper respiratory tract infection may have contributed to the cause, tr. 76, but he did not know what role, if any, it played in causing petitioner's GBS. Tr. 32.

In Dr. Younger's view, petitioner's clinical history was consistent with vaccine-induced GBS. Tr. 16. Dr. Younger interpreted a statement in petitioner's medical records to indicate that one of his treating physicians attributed his GBS to the Tdap vaccine. Tr. 29. Specifically, Dr. Younger believes that Dr. Fox's note in June 2010 stating "[p]ast medical history: [GBS] following tetanus immunization" indicates that Dr. Fox thought petitioner's Tdap vaccine caused his GBS. Tr. 29 (discussing Pet'r's Ex. 7 at 1); see also tr. 16. Dr. Younger interprets Dr. Fox's use of the word "following" to mean "caused." Tr. 29.

Dr. Younger opined that petitioner's other treating physicians, Dr. Adiga and Dr. Malik, did not have an opinion as to the cause of petitioner's GBS. Tr. 31. Dr. Younger disagreed with respondent's view that Dr. Adiga's notation "[w]hile [the tetanus] vaccine could have triggered [petitioner's GBS] (little too long), odds are viral URI more likely," Pet'r's Ex. 4 at 588, suggests that Dr. Adiga considered petitioner's GBS to have been caused by his infection. Tr. 31. According to Dr. Younger, "[a]lthough there was a sinusitis noted prior to the onset of [petitioner's] GBS symptoms [by petitioner's treating physicians], this was not explored as a causative factor by Petitioner's treating physicians." Pet'r's Ex. 9 at 3. In Dr. Younger's opinion, Dr. Adiga's notation stating "[w]hile the vaccine could have triggered it (little too long)," Pet'r's Ex. 4 at 588, is "trivial." Tr. 98.

When asked about Dr. Malik's notation that petitioner's condition was "probably post-infectious AIDP," Pet'r's Ex. 4 at 589, Dr. Younger omitted from the record the parenthetical information after that notation that reads "(URTI)."[23] Tr. 30-31; see also tr. 98-99. On cross-examination, Dr. Younger agreed, however, that Dr. Malik's notation "(URTI)" meant that Dr. Malik was referring to petitioner's upper respiratory tract infection. Tr. 99.

Dr. Younger was inconsistent about what role, if any, petitioner's upper respiratory tract infection played in causing his GBS. See tr. 19, 32, 33, 35. Dr. Younger agreed that it was "plausible" that petitioner's upper respiratory tract infection played a role in his GBS. Tr. 33. He opined that it could have been a "confounder." Tr. 19, 34. But Dr. Younger stated that he did not "know what role it (petitioner's upper respiratory tract infection) play[ed]" in petitioner's GBS, tr. 32, and he could not "give . . . a mechanism for the sinusitis" because he did not "know what agent is being invoked." Tr. 33.

b. Respondent's Expert, Dr. Chaudhry

Dr. Chaudhry opined that petitioner's Tdap vaccine did not cause petitioner's GBS. Dr. Chaudhry's opinion is informed, in part, by his belief that the tetanus infection does not cause GBS. Tr. 153. Rather, Dr. Chaudhry attributed petitioner's GBS to the upper respiratory tract infection he suffered for approximately three weeks before the onset of his GBS. This aspect of Dr. Chaudhry's testimony is discussed in detail in section III.C.iii below.

[23] Dr. Malik's notation states "Probably postinfectious AIDP (URTI)." Pet'r's Ex. 4 at 589. When Dr. Younger read this entry during the hearing, he left out the parenthetical information "(URTI)." See tr. 30-31.

c. Evaluation of the Evidence

The undersigned finds that petitioner has failed to provide preponderant evidence that his Tdap vaccine caused his GBS. Dr. Younger's interpretation of the evidence as suggesting that petitioner's Tdap vaccine caused his GBS is not persuasive.

In Dr. Younger's view, "[b]y the process of differential diagnosis, all potential causes thought possibly contributory by Mr. Rupert's doctors were ruled out, except sinusitis and the tetanus shot." Pet'r's Ex. 13 at 4. But then Dr. Younger concluded that petitioner's Tdap vaccine caused his GBS. Beyond his interpretation of the notes of petitioner's treating physician, Dr. Fox, Dr. Younger did not point to specific aspects of petitioner's clinical course that supported his theories. Simply stated, Dr. Younger did not provide persuasive factual support from petitioner's medical history that would explain why it was more likely than not that petitioner's Tdap vaccine, not his upper respiratory tract infection, caused his GBS.

Moreover, Dr. Younger's testimony regarding the opinions and records of petitioner's treating physicians appears disingenuous. A plain reading and interpretation is that both Dr. Adiga and Dr. Malik believed that petitioner's upper respiratory tract infection was the most likely cause of his GBS. Accordingly, Petitioner has failed to satisfy Althen Prong Two.

ii. Althen Prong Three: Medically Acceptable Timeframe

Under Althen Prong Three, petitioner must provide "preponderant proof that the onset of symptoms occurred within a timeframe for which, given the understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." de Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1352 (citing Pafford, 451 F.3d at 1358). The acceptable temporal association will vary according to the particular medical theory advanced in the case. See Pafford, 451 F.3d at 1358.

a. Petitioner's Expert, Dr. Younger

In his expert reports, Dr. Younger opined that the approximate five-week interval between petitioner's May 21, 2008 vaccination and the onset of his GBS around June 25, 2008, is medically acceptable for each of his theories of causation. Pet'r's Ex. 9 at 3; Pet'r's Ex. 13 at 3; tr. 18-19. Although he opined in his reports that the timeframe involved in petitioner's case was medically acceptable, Dr. Younger then testified at the hearing that he did not know what a medically acceptable timeframe would be for any of his theories. He stated that he did not know what a medically acceptable timeframe would be for his EAN theory because he could not "predict that animal timeframes would apply to humans." Tr. 79. Likewise, he conceded that he did not "have information about" what a medically acceptable timeframe would be for the molecular mimicry theory. Tr. 79.

> [Ms. Davis] . . . Is there an appropriate timeframe from exposure to vaccine to onset of GBS for your theory of EAN?
> [Dr. Younger] I don't know that -- well, the -- the EAN is an animal study.
> Q. Okay.

> A. So, I don't -- I don't predict that animal timeframes would apply to humans.
> Q. Okay. And for molecular mimicry?
> A. I don't have that information about -- I don't know that it's even well understood as being a specific number of hours, days, weeks, or months when specific events within that chain of events occurs.

Tr. 79. And Dr. Younger stated that there is no medically acceptable timeframe for his dual infection genesis theory.

> [Ms. Davis] Is there -- in order for this theory to be plausible, is there a specific timing between the vaccine and the infection that must occur?
> [Dr. Younger] No.
> ...
> Q. Okay. And it doesn't matter what the timing is between the vaccine and the infection? It could be one [] day; it could be one a week; it could be within three weeks, as long as it precedes --
> A. I don't think I have -- since this has not been extended to the literature or to other, you know, projections, I -- I don't think I feel comfortable rendering a time period, except to say that in this one particular instance, it was ideal.

Tr. 44. Further, Dr. Younger did not know of any studies that would support a five-week interval between tetanus vaccination and onset of GBS. See tr. 44, 79, 93.

b. Respondent's Expert, Dr. Chaudhry

Dr. Chaudhry opined that the approximately five-week interval between petitioner's Tdap vaccine and the onset of his GBS is too long to infer causation. See tr. 124. He opined, however, that the approximately three-week interval between petitioner's upper respiratory tract infection and the onset of his GBS was "exactly the timeframe" for an infection to lead to GBS. Tr. 124-25. According to Dr. Chaudhry, this timeframe is "well documented." Tr. 174.

c. Evaluation of the Evidence

The undersigned finds that petitioner has failed to provide preponderant evidence that the approximately five-week interval between his Tdap vaccine and the onset of his GBS is medically acceptable to infer causation. By his own admissions, Dr. Younger conceded that he did not know whether this timeframe was medically acceptable according to his own theories of causation. Further, he stated that his dual infection genesis theory does not have an applicable timeframe. Tr. 44. No evidence in the record corroborates or supports Dr. Younger's position that the temporal interval involved here is medically acceptable. Moreover, petitioner's treating physician, Dr. Adiga, documented that the onset of petitioner's GBS following his tetanus vaccine was a "little too long."[24] Pet'r's Ex. 4 at 588. Accordingly, petitioner has failed to satisfy Althen Prong Three.

[24] Petitioner suggests that Dr. Chaudhry considered a timeframe of up to six weeks to be medically acceptable because he cited epidemiological studies that looked for cases of GBS

C. Alternative Causation

Petitioner's medical records establish that he had an upper respiratory tract infection and sinusitis approximately three weeks prior to the onset of his GBS. See Pet'r's Ex. 2 at 3; Pet'r's Ex. 4 at 64, 66, 567, 605, 623. Petitioner does not dispute this fact. See Pet'r's Post-Hearing Br. at 7. Respondent and her expert, Dr. Chaudhry, consistently maintained that petitioner's upper respiratory tract infection was the sole cause of petitioner's GBS.

Under the Vaccine Act, compensation shall be awarded where the petitioner demonstrates the requirements set forth under the Act by a preponderance of the evidence, and "there is not a preponderance of the evidence that the . . . injury . . . is due to factors unrelated to the administration of the vaccine." § 300aa-13(a)(1)(A)-(B). The Act provides that "factors unrelated to the administration of the vaccine" are those "which are shown to have been the agent . . . principally responsible for causing the petitioner's illness, disability, injury, condition or death." Id. § 300aa-13(a)(2)(B). To satisfy her burden of showing an alternative cause of petitioner's injuries, respondent is "'required not only to prove the existence of [a factor unrelated], but also to prove by a preponderance of the evidence that the [factor unrelated] actually caused' the alleged injury. Knudsen, 35 F.3d at 549. Furthermore, [respondent] . . . also ha[s] to present sufficient evidence to prove that the alternative factor was the sole substantial factor in bringing about the injury." Deribeaux v. Sec'y of Health & Human Servs., 717 F.3d 1363, 1367 (Fed. Cir. 2013) (citing de Bazan, 539 F.3d at 1354). "Thus to establish alternative causation . . . [respondent] must satisfy the three prongs of Althen." Deribeaux v. Sec'y of Health & Human Servs., No. 05-306V, 2011 WL 6935505 (Fed. Cl. Spec. Mstr. Dec. 9, 2011) (citations omitted), aff'd, 717 F.3d 1363 (Fed. Cir. 2013).

i. Althen Prong One: Respondent's Medical Theory

In Dr. Chaudhry's "opinion, [petitioner's] tetanus vaccine didn't play any part" in his GBS. Resp't's Ex. H at 4. Dr. Chaudhry opined that petitioner's "upper respiratory tract infection led to his GBS," which was the result of a post-infectious process. Tr. 119-29; see also Resp't's Ex. H at 4. Dr. Chaudhry describes GBS as a "well-known post-infectious . . . immunological illness." Resp't's Ex. H at 4. In Dr. Chaudhry's view, "everyone agrees . . . that [an] upper respiratory tract infection leads to . . . a post-infectious neuropathy." Tr. 151.

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occurring up to six weeks after vaccination. Pet'r's Post-Hearing Br. at 6 (citing tr. 158); see also tr. 142-43 (Dr. Chaudhry discussing the Tuttle study (Resp't's Ex. E, Jessica Tuttle et al., "The Risk of Guillain-Barré Syndrome after Tetanus-Toxoid-Containing Vaccines in Adults and Children in the United States, 87 Am. J. Pub. Health 2045 (1997))). This argument misconstrues Dr. Chaudhry's opinion. Dr. Chaudhry stated that

> even though some epidemiological studies have taken five weeks and six weeks, I think most people would agree that if there is a vaccine-related event, it generally would occur fairly quickly. I would think within three weeks, but I would think even less, because infection is three weeks.

Tr. 148-49.

Dr. Chaudhry opined that an upper respiratory tract infection can cause an immune response, which results in GBS. See tr. 159-60. He asserts molecular mimicry is the mechanism by which this occurs. Tr. 159-60. A number of bacterial and viral infections, including *mycoplasma pneumoniae*, Epstein-Barr virus, *Campylobacter jejuni*, and cytomegalovirus, "have been known to generate a[n] [immune] response" that leads to an upper respiratory tract infection." Tr. 164; see also tr. 172, 173, 174. But, as noted earlier, the specific cause of petitioner's upper respiratory tract infection was never identified. The specific etiology of the upper respiratory tract infection is irrelevant, tr. 171, because both bacterial and viral infections can cause an immune response. Tr. 164. Further, Dr. Chaudhry opined that it would have been difficult to isolate the cause of petitioner's upper respiratory tract infection three weeks after it manifested. Tr. 171.

The record supports Dr. Chaudhry's opinion that an upper respiratory tract infection can cause an infectious process, which results in post-infectious GBS. The medical literature both parties submitted indicates that there is a well-documented association between upper respiratory tract infections and GBS. The authors of the Tuttle article (Resp't's Ex. E) stated that the "occurrence [of GBS] after viral and some bacterial infections has been well known." Resp't's Ex. E at 3. The authors of the Haber article[25] report that "[a]bout two-thirds of GBS cases occur several days or weeks after an apparent infectious illnesses, commonly . . . [an] upper respiratory tract infection." Resp't's Ex. F at 2; see also id. at 3 (discussing multiple infectious agents associated with GBS). Likewise, the authors of the van Doorn article (Resp't's Ex. C) noted that "GBS is most commonly a post-infectious disorder . . . [and] [i]n most GBS studies, symptoms of a preceding infection in the upper respiratory tract or gastrointestinal tract predominate." Resp't's Ex. C at 1-2. Dr. Younger agreed that an upper respiratory tract infection can cause GBS. See Pet'r's Ex. 13 at 3 (Dr. Younger stating that the only "two possible singular etiological causes of [petitioner's] GBS . . . [were his] vaccination and sinusitis"); see also tr. 25, 33-34, 76.

The medical literature both parties submitted also indicates that molecular mimicry is an accepted mechanism by which an infection can cause GBS. As the Hughes article (Pet'r's Ex. 11) states, there is "strong evidence of a causative association" between GBS and *Campylobacter jejuni*, cytomegalovirus, Epstein-Barr virus, and *Mycoplasma pneumonia*. Pet'r's Ex. 11 at 4. The authors of the van Doorn article (Resp't's Ex. C) also identified *Campylobacter jejuni*, cytomegalovirus, Epstein-Barr virus, *Mycoplasma pneumonia*, and *Haemophilus influenzae* as "well defined types of infection[s] related to GBS." Resp't's Ex. C at 2. Both *Campylobacter jejuni* and *haemophilus influenzae* are thought to cause GBS via molecular mimicry. Resp't's Ex. C at 3.

The parties do not dispute that petitioner had an upper respiratory tract infection with an unknown viral or bacterial cause. Likewise, the parties do not dispute that some infections, including upper respiratory tract infections, can cause GBS. Although petitioner's treating

[25] Resp't's Ex. F, Penina Haber et al., "Vaccines and Guillain-Barré Syndrome," 32:4 Drug Safety 309 (2009).

physicians did not identify a specific cause of petitioner's upper respiratory tract infection, they considered it the most likely cause of his GBS. Respondent need not identify the specific viral or bacterial infection that caused petitioner's upper respiratory tract infection to satisfy Althen Prong One. See Knudsen, 35 F.3d at 549-50.

The undersigned finds that respondent has provided preponderant evidence showing that an upper respiratory tract infection can cause GBS. Accordingly, respondent has satisfied Althen Prong One.

ii. Althen Prong Two: Logical Sequence of Cause and Effect

Noting that approximately two-thirds of GBS patients report similar antecedent symptoms, tr. 159, Dr. Chaudhry opined that there "is a very well-established cause and effect relationship" between upper respiratory tract infections and GBS. Tr. 154. Dr. Chaudhry summarized petitioner's clinical course as a "sequence of events . . . from upper respiratory tract infection, followed by rapidly progressive weakness, areflexias, high spinal fluid protein, [and] demyelinating findings on EMG." Tr. 116.

Dr. Chaudhry opined that petitioner's clinical course presents a "textbook" case of GBS caused by an upper respiratory tract infection. See tr. 116. Although Dr. Chaudhry acknowledges that there was no test that could have definitively diagnosed the cause of petitioner's GBS, tr. 91, he opined that petitioner's cerebrospinal fluid ("CSF") test was indicative of a post-infectious process because it did not contain cells. Tr. 118. In Dr. Chaudhry's view, "[i]f there were cells, then you would think that there is direct infections." Tr. 118.

The medical literature also indicates that there is a well-known cause and effect relationship between upper respiratory tract infections and GBS. See, e.g., Resp't's Ex. C at 2. About two-thirds of GBS cases are preceded by an antecedent infection, commonly an upper respiratory tract infection. Resp't's Ex. F at 2. Dr. Chaudhry explained that "[f]ever . . . cough . . . and nasal congestion . . . are frequent[] antecedent symptoms in GBS," and noted that "these [symptoms] were noted in the 3 weeks prior to [petitioner's] . . . GBS." Resp't's Ex. A at 4 (citing the van Doorn article (Resp't's Ex. C)).

The opinions of petitioner's treating physicians are afforded substantial weight. Capizzano, 440 F.3d at 1319-20. Notably, Dr. Younger indicated that he would "rely on [his]… infectious disease consultants" in diagnosing the cause of a patient's GBS if that patient had a history of an upper respiratory tract infection prior to the onset of GBS. See tr. 101. Dr. Adiga, an infectious disease specialist, considered petitioner's Tdap vaccine but opined that it was more likely that his upper respiratory tract infection caused his GBS. Pet'r's Ex. 4 at 588. Likewise, Dr. Malik believed petitioner's upper respiratory tract infection caused his GBS. Pet'r's Ex. 4 at 589.[26] The opinions of petitioner's treating physicians, as well as that of Dr. Chaudhry, are

[26] Petitioner asserts that Dr. Fox considered petitioner's Tdap vaccine as a potential cause of his GBS. See Pet'r's Post-Hearing Br. at 8 (citing Pet'r's Ex. 2 at 3; Pet'r's Ex. 7 at 1); tr. 28. Dr. Fox noted a temporal relationship between petitioner's Tdap vaccine and the onset of his GBS,

further confirmed by the medical literature on which Dr. Chaudhry relied, which indicates that petitioner's clinical course was consistent with post-infectious GBS.

The undersigned finds that respondent has provided preponderant evidence of a logical sequence of cause and effect showing that petitioner's upper respiratory tract infection caused his GBS. Accordingly, respondent has satisfied her burden under Althen Prong Two.

iii. Althen Prong Three: Medically Acceptable Timeframe

Dr. Chaudhry opined that the three-week interval between petitioner's upper respiratory tract infection and the onset of his GBS is a medically acceptable timeframe to infer causation-in-fact. Tr. 157-58. Likewise, because petitioner's treating physicians believed that petitioner's GBS was caused by his upper respiratory tract infection, they presumably considered the temporal interval to be medically acceptable. See Contreras v. Sec'y of Health & Human Servs., 107 Fed. Cl. 280, 299 (2012); Andreu, 569 F.3d at 1376. Further, Dr. Younger did not dispute that the timing was medically acceptable. See Pet'r's Ex. 13 at 3.[27]

The medical literature the parties submitted addresses the issue of timing. The authors of the Haber article (Resp't's Ex. F) state that "[a]bout two-thirds of GBS cases occur several days or weeks after an apparent infectious illnesses, commonly . . . [an] upper respiratory tract infection." Resp't's Ex. F at 2. Likewise, the authors of the van Doorn article report that that "about two-thirds of [GBS] patients have symptoms of an infection in the 3 weeks before the onset of weakness." Resp't's Ex. C at 2.

The undersigned finds that respondent has provided preponderant evidence that the approximate three-week interval between petitioner's upper respiratory tract infection and the onset of his GBS is a medically acceptable timeframe to infer causation. Accordingly, respondent has satisfied her burden under Althen Prong Three.

IV. Conclusion

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but he did not state that petitioner's vaccine was causative. See Caves v. Sec'y of Health & Human Servs., 100 Fed. Cl. 119, 130 (2011) (observing that a treating physician's statement noting "a mere temporal association between the vaccine and petitioner's [injury]" does not necessarily "constitute a determination on the issue of causation").

[27] Dr. Younger's testimony regarding the timeframe between petitioner's upper respiratory tract infection and the onset of his GBS is inconsistent. At the hearing, he initially stated that it was "[s]omewhere between one and two weeks," tr. 45, but later agreed that petitioner had a three-week history of an upper respiratory tract infection prior to the onset of his GBS. Regardless, petitioner's medical records establish that he had a three-week history of upper respiratory tract infection symptoms prior to the onset of his GBS, Pet'r's Ex. 2 at 3, which Dr. Younger considered to be an "appropriate timeframe for consideration as causal." Pet'r's Ex. 13 at 3.

For the reasons discussed above, the undersigned finds that petitioner has not established entitlement to compensation and his petition must be dismissed. In the absence of a timely filed motion for review filed pursuant to Vaccine Rule 23, the clerk is directed to enter judgment consistent with this decision.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master